

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 15-17, in the reply filed on 3-11-2008 is acknowledged. Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Claim Objections***

Claim 27 is objected to because of the following informalities: said claim recites "wide" instead of "width." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "the hernia defect." There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelissier (US 6,669,735).

Pelissier discloses a method for treating a hernia comprising the steps of exposing a hernia defect, providing a prosthesis comprising a portion of a truncated cone (Figure 6) comprising a crescential cross-section, a first surface, and a second surface wherein the first surface forms at least one incomplete channel, introducing the prosthesis, and providing a relatively pressure-free passage of an anatomical structure through the prosthesis. (See Abstract) The method is for treatment of inguinal or femoral hernia, and may be placed in the peritoneal compartment of the abdominal wall. The anatomical structure is partially enclosed in said channel. Pelissier does not disclose the pressure and compression exerted onto the anatomical structure contained in the channel, but does teach that the channel is provided such that pressure on said anatomical structure will be minimized. Furthermore, the pressure and compression is affected by the size of the device, the size of the channel, and the size of the anatomical structure. It would have been obvious to one of ordinary skill in the art to provide the prosthesis such that it exerts minimal pressure and compression on the anatomical structure such that it compresses the anatomical structure less than 1-10% of its width at a pressure in the range of 2 to 10 mm Hg in order to minimize damage done to said structure. Furthermore, it has been held that it is within the knowledge of one of ordinary skill in the art to determine an optimal range for the functionality of a method or

device. The channel comprises a cut-out for a vessel. At least 30% of the circumference of said anatomical structure is enclosed by the prosthesis.

Regarding claim 27, the prosthesis is flexible and is placed around an anatomical structure. Placing the prosthesis around an anatomical structure inherently requires flexing it from a rest position to an open position to increase the width of access to the channel for receiving the anatomical structure. Alternatively, it would have been obvious to flex the prosthesis to fit it around a larger structure.

Claims 26, 29, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelissier (US 6,669,735) in view of Nicolo (US 6,652,595).

Pelissier discloses all elements of said claims except that the prosthesis includes a flange that transitions between a collapsed and an extended position to attach to surrounding musculature. Nicolo teaches that it was well known to provide a hernia prosthesis with extendable flanges that attach to musculature to anchor the prosthesis (See Figures 7a-7c and 10a-10d). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Pelissier by providing an extendable flange to attach to surrounding musculature to anchor the prosthesis as taught by Nicolo. When treating an inguinal canal, the flange would extend to the musculature of the inguinal canal. It would have been obvious to extend the flange inferomedially since the orientation of the prosthesis by the physician is a matter of design choice.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

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